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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,532	11/29/2003	Thomas D. Reed		3265

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HASSE & NESBITT LLC  
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EXAMINER

CARLSON, KAREN C

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/724,532

Applicant(s)

REED, THOMAS D.

Examiner

Karen Cochrane Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-10 is/are allowed.
- 6) ☐ Claim(s) 1-3, 11-19 is/are rejected.
- 7) ☒ Claim(s) 4-7 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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This Office Action is in response to the paper filed November 1, 2005. Claims 1-20 are currently pending and are under examination.

The claimed invention is found in SN 60/430,322. Therefore the priority date of the instant invention is December 2, 2002.

**Withdrawal of Objections and Rejections:**

The objection to the disclosure because of informalities is withdrawn.

The rejection of Claims 1-3, 5, 6, and 11-14 under 35 U.S.C. 112, first paragraph, is withdrawn.

The rejection of Claims 1-3 and 11-13 under 35 U.S.C. 102(b) as being anticipated by Kimura et al. (1997; J. Biol. Chem. 272(24): 15061-15064) as set forth in the previous Office Action, is withdrawn.

The rejection of Claims 1, 5, 6, 11, and 14 under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Kimura et al. (1997; J. Biol. Chem. 272(24): 15061-15064) and Kimura et al. (1996; J. Biol. Chem. 271(36): 21726-21731) as set forth in the previous Office Action, is withdrawn.

The rejection of Claims 1, 4, 8, and 15 (SEQ ID NO: 3, 5) under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Kimura et al. (1997; J. Biol. Chem. 272(24): 15061-15064) as set forth in the previous Office Action, is withdrawn.

The rejection of Claims 7, 9, 10, and 16 under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Kimura et al. (1997; J. Biol. Chem. 272(24): 15061-15064) as

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applied to Claims 1, 4, 8, and 15 above, in view of Kimura et al. (1996; J. Biol. Chem. 271(36): 21726-21731) as set forth in the previous Office Action, is withdrawn.

**Maintenance of Rejections:**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed polypeptide is not stated to be isolated or purified, thus reading on the product in nature.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note that claim 15 is pending.

In Claim 15, SEQ ID NO: 4 and NO: 6 are antisense strands. Therefore, linking a second nucleotide sequence encoding a protein targeted to a sacro(endo)plasmic region to an antisense that does not encode a polypeptide would not result in targeting a protein targeted to a sacro(endo)plasmic region.

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Applicants urge that Claim 15 has been canceled and that amendments to Claim 16 corrects this problem by turning the antisense strands into sense or coding strands. Note that Claim 15 is pending and refers to SEQ ID NO: 3, 4, 5, and 6. SEQ ID NO: 3 and NO: 5 are coding strand, and thus amended claim 16 makes these strands antisense.

**New Rejections:**

Claims 19 and 20 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 3 and 4. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claims 3 and 4 be found allowable, claims 19 and 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-3, 11-13, 17, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kimura et al. (1997; J. Biol. Chem. 272(24): 15061-15064).

As noted in the instant specification at page 4, Kimura et al. mutated each phospholamban (PLN) transmembrane (domain II) amino acids Leu31(amino acid 9 of SEQ ID NO: 1)-Leu52 (amino acid residue 30 of SEQ ID NO: 1), to Ala. (page 15062, left col.). Leu31(9)Ala, Asn34(12)Ala, Phe35(13)Ala, Ile38(16)Ala, Leu42(20)Ala, Ile48(26)Ala, Val49(27)Ala, and Leu52(30)Ala mutations resulted in loss of function for PLN (Table 1 and page 15063, para. 2). Thus, Claims 17 and 18 are anticipated by Kimura et al.

Additionally, Kimura et al. teach PLN double mutants comprising Asn34(12)Ala/Ile48(26)Ala. Thus, Claims 1-3 and 19 are anticipated by Kimura et al.

Kimura et al. expressed these mutated PLN transmembrane domain amino acids from HEK-293 cells. Therefore, Kimura et al. were in possession of the nucleic acid encoding these mutant PLNs (Claims 11-13).

Claims 8-10 are allowed.

Claims 4-7 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**KAREN COCHRANE CARLSON, PH.D**  
**PRIMARY EXAMINER**